**From:** Oriente, Michael [/O=MCKESSON/OU=NORTH AMERICA/CN=RECIPIENTS/CN=ESHJXSL]
**Sent:** 3/7/2008 7:14:55 PM
**To:** Walker, Donald [donald.walker@mckesson.com]; #PGRDRC [pgrdrc@mckesson.com]
**Subject:** Regulatory Meeting 3/5 & 3/6

Team,
Here are the notes from our meeting.

*Michael P. Oriente*

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# Regulatory Meeting, Carrollton 3/5 and 3/6/2008

**Attendees:**
Don Walker
Bruce Russell
Gary Hilliard
Tom McDonald
Tracy Jonas
Bill Mahoney
Michael Oriente

Wednesday, 3/5/2008

- **Items that will be covered during the meeting:**
  - Memorandum of Agreement
    - 2 to 3 weeks expect sign offs with the DEA
    - New CSMP Program
  - Responsibilities
  - Communication Plan / Roll Out
  - Director Roles
  - Set Operational Thresholds
  - RNA Group CSMP Introduction Meeting

- **Memorandum of Agreement:**
  - 3 Points
    - Covered Conduct
    - Foundational to how we see it
    - Program to Work / Need to Demonstrate Control
    - License suspension to take place
    - Agreement will take effect 5 days after signing
    - Agreement will cover all 39 McKesson DEA registrants
    - Covered Conduct - 3 points
      - Failure to maintain adequate controls against diversion
      - Failure to report thefts or loses of controlled substances
      - Failure to detect and report suspicious orders of controlled substances

Tracy asked what is considered a suspicious order and suggested possibly using the term excessive until it can be determined to truly be suspicious.

QUESTION: Can MMS use quarterly review process in place of a monthly on?

The new process for Control Substance Monitoring Program, CSMP, will monitor all control substances.

QUESTION: What should MMS do if not on report submittal list and they get audited?

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- **Terms and Conditions:**

  The new CSMP suspicious order process being developed will be set up to report to the DEA at Headquarters level and not the field offices. The DEA will handle communication from HQ to field offices of this reporting change. There have been different messages coming from DEA field offices and DEA Headquarters. A questions was asked, does the Board of Pharmacy need to know when a customer is cut off? This is not required.
  The program will be implemented to detect and prevent diversion of controlled substances.
  Reporting will take place every 2 days via EDI of all CS to DEA. This report will begin 120 days after agreement is signed. This reporting will be in effect for 2 years,

- **Suspension:**
  - There will be a suspension to distribute schedule III Hydrocodone and Alprazolam at Lakeland and Conroe DC's only
  - Base codes 9805, 9806 and 2882 ( Gary to validate correct base codes)
  - The suspension will end after inspection targeted at 6 months by DEA

  The fines are $10,000 per violation. This agreement process has been 2 years in the works. Large investigative costs incurred by DEA hence the large fine amount.

- **Civil Penalties:**
  - $13.25M (fine could have been as high as $46M)
  - 6 DC's involved
    - Lakeland
    - Landover
    - Conroe
    - Denver
    - Salt Lake City
    - Sacramento

- **Factors influencing DEA Civil Penalty:**
  - There were many factors influencing the decision. It involved multiple DC's, estimated to be over 4,600 violations, DEA looked at multiple time periods, shipments to pharmacies that turned out to be internet pharmacies, shipping millions of dosages to a couple of pharmacies that later were indicted.

- **Termination of the Suspension:**
  - DEA will review our compliance
  - The review period will take place 90 to 150 days after the signing
  - The review could take place at 8 different DC locations, including
    - Lakeland
    - Conroe
    - Landover
    - 5 other McKesson DC's
    - DC's will be provided a 48 hour advance notice of inspection

- **Termination of the Suspension: - cont.**

  - Failure to maintain effective controls against diversion, failure to detect and report suspicious order(s) and failure to investigate new customers' legitimacy to purchase controls will result in unsatisfactory reviews.
  - DEA will provide preliminary conclusion at exit interview

Our documentation of must be in order. **WE CAN NOT HAVE A REPEAT OCCURANCE.** The DEA brought in a team of agents to the Conroe DC to conduct the investigation.

QUESTION: What work and methodology has Cardinal and ABC done on threshold setting?

- **Roles and Responsibilities:**

You all will be the decision makers for the Region. You should be actively engaged with Sales, Operations, VPDO and SVP. You will review and approve all new customers. It will be your responsibility to review all blocked orders. The directors will adjust any thresholds that need reviewing. Perform customer analysis. Perform site visits. In the decision process you are not on an island, out on your own. There are a lot of resources that are available to you. Let Don and Bruce know of any needs. We will be provided a list of people of who to go to in Licensing, Legal, Marketing, and different segments of Sales, RNA and Independent.

We need to have active engagement. There should be open communication with the DCM's. Get familiarized with DC personnel performing CSMP responsibilities. Make sure to partner up with them. Work with your VPDO and VPGM to get on their weekly conference call with the DCM's. Provide the training and education of the CSMP to your respective regions. Work on to improve the relationships with your DC's DEA agents. The DCM must also continue the relationship with the DEA. **The contact person to the DEA needs to change from the ARCOS Clerk to the DCM/DO.** Know what the ARCOS Clerks communication escalation is within the DC management team. Think about scheduling an ARCOS meeting in your Region. There needs to be fully active engagement.

There will be a policy change for the regulatory Directors to evaluate all new customers. Keep in mind the scope. This will be similar to a credit review. Establish the legitimate need, appropriate quantity for business type, set customer threshold and perform research. This should include photos of the pharmacy, copy of licenses and customer questionnaire.

Information on customer credit swing fluctuations to be looked at if this information could assist us with customer evaluations.

QUESTION: Does the Promotional Accounting Rebate Incentive System (PARIS) dispensing data take into account Medicaid and Medicare sales?

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- **Roles and Responsibilities: - cont.**

  You will review all blocked orders. Conduct Tier I and II reviews. Make necessary changes to customer thresholds as appropriate when required. Perform Tier III review for suspicious customers and report to DEA. The Tier I and II reviews will be clearer; the Tier III will be the gray ones needing more analysis.

- **RNA Meeting**
  - Don introduced the CSMP
  - Thresholds will be set using 12 months sales data
  - Decision to be made whether customer thresholds should be set at 80% or 90% before first notification?
  - An ordering floor will be set
  - TCR Process – Threshold Change Request
  - There will be a compliance person reporting to Elaine to assist with CSMP
  - RNA Team to work on customer on customer on boarding
  - RNA Team to contact accounts to inquire how they want to be included on threshold setting

  QUESTION: How will overall customer Service Levels be measured after omit threshold is met?

- **Analysis and Investigation:**
  - Know your customer
  - BW queries available to gather information on purchases
  - Training will be available for whoever needs it
  - Six Sigma is also available as a resource
  - Evaluate the high volume customers
    - May have 10-25 customers in this category meeting the criteria
    - Documentation will be the key
    - Share ideas between ourselves
    - Take photos of the sites visited
    - Cameras have been approved for each director to be expensed
      - Hold off on any GPS purchases
  - Relay Health may have report data that they can make available to the team for analysis

- **Tomorrow we will cover:**
  - Threshold setting by customer type and drug base code
  - Customer Review Process
    - Tier I, II & III
  - Documentation
  - SOP's

# Regulatory Meeting, Carrollton 3/5 and 3/6/2008

**Attendees**
Don Walker
Bruce Russell
Gary Hilliard
Tom McDonald
Tracy Jonas
Bill Mahoney
Michael Oriente
Dave Gustin on Conf Call

Thursday, 3/6/2008

- **Thresholds:**
  - How should they be established and how should they be monitored?
  - New customers settings
  - Tier Review Process
  - When setting the % of controls to purchase; are they for legitimate reasons? Look at large %, large quantities
  - Document all information back referencing back to the regulation and is it legitimate?
  - The key is the appropriate documentation
    - **Know the customer**
  - The key secret is getting the thresholds right from the start up
  - Use common approach amongst the directors across Regions
  - For the Denver DC, data was sorted and Tracy looked at the customer purchases history then resorted by drug class and thresholds.
  - Find customers to focus on, run the data and perform analytics. Look at % of controls to total purchases. Bill will check on Volakos Report (name to be changed) that all DC's have the visibility to view % of control purchases to total Rx purchases.
  - What should the bottom threshold be set at? 5,000 or 8,000
    - A consensus was reached that it be set at 5,000 not the 1,000 that was first developed on the systemic review. This should eliminate a lot of unnecessary reviews and extra releasing of blocked orders that have no suspension to them.

- **Building the Methodology**
  - There will no longer be quarterly buys on control substance generics
  - In the next 60 to 120 days (except Denver) get all threshold tables set
  - Consistency is key – lock step and unified approach

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- **Building the Methodology - cont**

  An analysis that Don had received from Keith showed for June to August, Hydrocodone sales by dosage for percent of customers was:

| DOSAGES | % of CUSTOMERS | TOTAL CUSTOMER % |
|---|---|---|
| < 10k | 77.3% | |
| 10k – 15k | 11% | |
| 15,001 – 20k | 4.3% | |
| | | 20k = **93.1%** |
| 20,001 – 30k | 4.3% | |
| 30,001 – 50k | 1.7% | > 20k = 50k = **6.0%** |
| | | |
| 50,001 – 100k | .5% | |
| 100,001 – 200k | .2% | |
| >200k | .1% | > 50k = **< 1%** |

- **> 10k Group**
  - No Review necessary by Regional Director
  - DC to perform daily order processing

- **20k to 50 k Group**
  - Perform Tier I review
    - If not satisfactory, perform Tier Level II review
  - Research % of control Purchases to total Rx purchases
    - Bench mark 12%
  - Check % of specific drug to control purchases
  - Review of sales history

ACTION ITEMS: Make sure that the Volakos Report to obtain the % of a control substance purchase to total Rx purchases is available at each DC. Bill and Bruce to take this to do.

Develop a data base on customers. Gary and Don to take this to do. Gary you got this one. There is the share point data and all the information that Jan Phillips has collected. Also to check with Keith on what data is available.

- **> 50 k Group**
  - Perform every task for customers below 50k, plus
  - Evaluate against Family Type
  - Site visit with photos
  - Site visit documentation
  - Any additional documents that support business model

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- **New Customers**
  - Sales Rep will complete customer questionnaire
  - Questionnaire submitted to Regulatory Director for approval
  - A site visit performed at the "ship to" address for the customer
  - License validation

- Tier I Review – performed by DC
  - Perform data analysis

- Tier II Review – performed by Regulatory Director
  - Level I Review, plus
  - Site Visit

- Tier III Review – performed by Regulatory VP
  - Level II Review, plus
  - In-depth analysis
  - Senior Management engagement

ACTION ITEM: Need to formulate reason codes for threshold adjustments. They should be plain text and not numerical codes. Michael to take this to do.